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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,594	11/28/2005	Marc Blondel	0070663-000002	1460
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EXAMINER				
ANDERSON, JAMES D				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
07/01/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

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### Office Action Summary

**Application No.**

10/531,594

**Applicant(s)**

BLONDEL ET AL.

**Examiner**

JAMES D. ANDERSON

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/22/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-8 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 11-15 and 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 November 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/6/2010.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Formal Matters***

Applicants' response and amendments to the claims, filed 4/22/2010, are acknowledged and entered. Claims 1-8, 11-15, and 18-21 remain withdrawn from consideration. Claims 16 and 17 are presently under examination.

### ***Change of Examiner***

The examiner assigned to the instant application has changed. The new examiner is James D. Anderson. Contact information is provided at the end of this Office Action.

### ***Response to Arguments***

Applicants' arguments, filed 4/22/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Information Disclosure Statement***

Receipt is acknowledged of the Information Disclosure Statement filed 5/6/2010. The Examiner has considered the references cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

### ***Drawings***

The translated drawings were received on 11/28/2005. These drawings are acceptable to the Examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16 and 17 remain rejected under 35 U.S.C. 102(a) as being anticipated by **Bach *et al.***

Applicants argue that Bach is not prior art because it was published online August 10, 2003, and the instant application, claims, and was granted, a priority date of October 18, 2002 based upon FR 0213022.

Applicants' arguments have been fully and carefully considered but they are not deemed persuasive. The instant application is a 371 of PCT/FR2003/003101, filed October 20, 2003, and claims foreign priority under 119(a)-(d) and (f) to French Patent Application Nos. FR02/13022, filed October 18, 2002, and FR03/08289, filed July 7, 2003. The French applications to which the instant application claims priority are not in English. As such, a certified English translation of FR02/13022, filed October 18, 2002, is required to overcome Bach as a prior art reference under 35 U.S.C. 102(a). Without such an English translation, the Examiner has no way of determining whether Applicants' claimed invention is supported under 35 U.S.C. 112, 1st Paragraph in the FR02/13022 application. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Accordingly, the rejection of claims 16 and 17 as being anticipated by Bach *et al.* under 35 U.S.C. 102(a) is maintained for the reasons of record.

### ***Claim Rejections - 35 USC § 103 – New Ground of Rejection***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(c), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Macfarlane et al.** (USP No. 6,479,504 B1; Issued Nov. 12, 2002; Filed June 16, 2000).

Macfarlane *et al.* disclose compositions and methods for inhibiting stimulation of the immune system (Abstract). Macfarlane *et al.* disclose therapeutic compositions for inhibiting stimulation of the immune system using chloroquine, its structural analogs and derivatives, or other weak bases (col. 12, lines 13-21; col. 21, lines 59-67). In this regard, Macfarlane *et al.* disclose that chloroquine and a number of its structural analogs specifically and powerfully inhibit the immunostimulatory effect of unmethylated CpG-motifs at nanomolar concentrations. A large variety of analogs have been constructed, many of which possess some inhibitory effect on the immunostimulatory capacity of CpG-motifs (col. 14, lines 55-60; FIGURE 1). As shown in Figure 1O, compound 354 S-10 is one such analog possessing some inhibitory effect on the immunostimulatory capacity of CpG-motifs. This is a compound of the instant claims when R' is  $\text{NH}-(\text{CH}_2)_3\text{N}(\text{CH}_3)_2$  and p and n are 0.

Accordingly, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate a therapeutically effective amount of compound 354 S-10 as disclosed in Macfarlane *et al.* in a pharmaceutically acceptable carrier for use in the inhibition of the immunostimulatory effects of CpG-motifs as suggested and motivated by the teachings of Macfarlane et al.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/6/2010 prompted the new ground(s) of rejection

presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/  
Primary Examiner, Art Unit 1614

June 28, 2010